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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853
7590 Chiron Corporation Intellectual Property R440 PO Box 8097 Emeryville, CA 94662-8097			EXAMINER NEGIN, RUSSELL SCOTT	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 06/25/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/018,470

Applicant(s)

FRASER ET AL.

Examiner

RUSSELL S. NEGIN

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-82 is/are pending in the application.
- 4a) Of the above claim(s) 3-21 and 24-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Comments

Applicants' amendments and request for reconsideration in the communication filed on 26 March 2008 are acknowledged and the amendments are entered.

Claims 3-21 and 24-82 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10 June 2005.

Claims 1-21 and 24-82 are pending in this application, and claims 1-2 are examined in this Office action.

Claim Objections

The following objection is newly applied:

Claim 1 is objected to because of the following informalities:

Instant claim 1 comprises 4 steps. However, the conjunction "and" concludes the second and third steps; it should only conclude the third step of instant claim 1.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

The following rejection is reiterated from the previous Office action:

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The following analysis of facts of this particular patent application follows the analysis suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility". Note that the text of the Guidelines is italicized.

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result.

In the instant case, the claimed invention does not "transform" an article or physical object to a different state or thing because it is a method for identifying an amino acid sequence. This does not preclude the subject matter to be patentable as, for eligibility analysis, as

physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that produces a useful, tangible and concrete result. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial

exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory. (Guidelines, p. 20)

The question is thus whether the final result achieved by the claimed invention satisfies all three criteria of being useful, and concrete, and tangible.

Furthermore, the useful, tangible, and concrete result must be recited in the claim itself, rather than addressed in specification.

The instant claims are drawn to computational method for identifying an amino acid sequence. However, as claimed, the method does not produce a tangible result. For example, the method as claimed may take place entirely within the confines of a computer or a human mind without any communication to the outside world and without using or making available for use, the results of the computation. Thus, the instant methods of the claims may not produce any tangible result. This rejection may be overcome by indicating the identified amino acid sequence can be output to a display.

Response to Arguments:

Applicant's arguments filed 26 March 2008 have been fully considered but they are not persuasive. Applicants argue that their amendments overcome the rejection of record. This is not persuasive because there is an embodiment of the instant invention in which the identified amino acid sequence can be output to a computer readable media, which may only be accessible by other computers and not a user.

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Consequently, since an embodiment of the claimed invention is not tangible, the entire set of claims is considered not statutory.

Claim Rejections - 35 USC § 103

The following rejection is reiterated from the previous Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribot et al.

The claims are drawn to a method for identifying an amino acid sequence from the N. meningitidis serogroup B strain MC58 genome, comprising the steps of:

- providing a computer database comprising the *N. meningitidis* serogroup B strain MC58 genome sequence of SEQ ID NO:1;
- searching for putative open reading frames or protein-coding sequence within the computer database;
- identifying an amino acid sequence corresponding to the searched putative open reading frame or protein coding sequences; and
- outputting the identified amino acid sequence to a user display or to a computer readable media.

Claim 2 further comprises searching the computer database containing SEQ ID NO:1 for an initiation codon; and searching for an in-frame termination codon downstream of the initiation codon.

Ribot et al. disclose a method of automated DNA sequence analysis of PCR fragments using a dye terminator reaction method (page 57, lines 2-7) for identifying serogroup B amino acid sequences comprising the step of computer assisted analysis (page 57, lines 5-7) for putative open reading frames (see Figure 1 of Ribot et al. and SEQ ID NO 6 and SEQ ID NO 3 of Ribot et al.) or coding an amino acid sequence with *N. meningitidis* nucleotide sequence (SEQ ID NO: 1 of Ribot et al.). As shown in Ribot et al., SEQ ID NO: 1 of Ribot et al. comprises the initiation codon (i.e. ATG, see SEQ ID NO:1 of Ribot et al., line 1, positions 16-18), an in frame termination codon (see SEQ ID NO:1 of Ribot et al., line 1, position 1100, and 1148). Ribot et al. discloses a method for searching ORFs or protein coding sequences of *Neisseria meningitidis* (Ribot et al.,

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pages 57-59 expands on this analysis). Additionally, Figures 5-7 of Ribot et al. comprise a database of several SEQ ID NOs; discussed on page 6, lines 20-30 of Ribot et al. with protein (i.e. amino acid) sequences assigned to the ORF.

However, Ribot et al. does not discuss a analysis of the entire instant SEQ ID NO. 1 from *N. meningitidis* claimed in the instant application.

The computer system and its method of use of identifying and analyzing sequences of biomolecules (i.e. SEQ ID NO 1 of the instant application) as stated in the instant set of claims differs from the claimed invention only in the content of the sequence used in the search. The MPEP states in 2106.01:

When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The above paragraph cites four court decisions which, when taken together, give the same message and theme regarding prior art and patentability of computerized media

The difference between Ribot et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the method functions, i.e., the database of the claimed computer method does not alter the computer method to perform a different function

than the computer system of Ribot et al. Therefore, the sequence information of the instant claims do not patentably distinguish the claim from the prior art.

Response to Arguments:

Applicant's arguments filed 26 March 2008 have been fully considered but they are not persuasive.

In response to arguments regarding Court decisions regarding nonfunctional descriptive material, it is maintained that Ribot et al. teaches all the claimed method steps. The court decisions are merely provided for further edification behind the principle of patentability designated to non-functional descriptive material. As explained above, since the sequence in the instant set of claims is non-functional descriptive material, it does not patentably distinguishable the claims from prior art that teaches all of the embodiments of the claim except this non-functional descriptive material.

Applicant continues to argue that the sequence itself is useful on page 13 of the Remarks. This argument is not persuasive because the rejection is not one under 35 U.S.C. 101 regarding utility, but is one of obviousness under 35 U.S.C. 103. Additionally, the sequence is given patentable weight (note that otherwise the rejection would be made under 35 U.S.C. 102); however, the sequence does not patentably distinguish the claimed method from Ribot et al. because, as described above, the sequence in the database claimed is nonfunctional descriptive material.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the central PTO Fax Center. The faxing of such pages must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Negin, Ph.D., whose telephone number is (571) 272-1083. The examiner can normally be reached on Monday-Friday from 7am to 4pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Marjorie Moran, Supervisory Patent Examiner, can be reached at (571) 272-0720.

Information regarding the status of the application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information on the PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RSN/
Russell S. Negin, Ph.D.
14 June 2008

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631